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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Farhad Parhami

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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,945	Applicant(s) PARHAMI, FARHAD	
	Examiner MARIA LEAVITT	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15-41 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,9,10,18,22,27 and 29-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8,11,12,15-17,19-21,23-26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-12-2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Status of claims. Claims 1-12, 15-41 are pending. Claim 1 and 29 have been amended, claim 13 and 14 have been cancelled by Applicants' amendment filed on 01-09-2009. Claims 4, 5, 9, 10, 18, 22 and 27 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, and claims 29-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
3. Therefore, claims 1-3, 6-8, 11, 12, 15-17, 19-21, 23-26 and 28 are currently under examination to which the following grounds of rejection are applicable.

Withdrawn Rejections/objection in response to Applicants' arguments or amendments:

Objection Specification

In view of Applicants' submission of a substitute specification to paragraph [0068] to properly identify the disclosed nucleotide sequences with SEQ ID NO, objection to the specification has been withdrawn.

Claim objection

In view of Applicants' cancellation of claims 13 and 14, objection to claims 13 and 14 under 37 CFR 1.75, as being a substantial duplicate of claims 1 and 2 is rendered moot.

Rejections/objection maintained in response to Applicants' arguments or amendments:

Claim Rejections - 35 USC § 103(a)

Claims 1-3, 6-8, 11-17, 19-21, 23-26 and 28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paralkar et al., US Publication no. 20040176423 (Date of Publication September 9, 2004), in view of Parish et al., (1995, Lipids, pp. 247-251) and further in view of Wang et al. (Clinical Orthopaedics and Related Research, 2000, 370: 295-310).

Response to Applicants' arguments as they apply to rejection of claims 1-3, 6-8, 11-17, 19-21, 23-26 and 28 under 35 U.S.C. 103(a)

At pages 10 and 11 of the Remarks filed on 09-11-2008, Applicants essentially argue that Paralkar et al., teaches that statins inhibit 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, and that statin are the only specific HMG-CoA reductase taught by Paralkar useful in promoting bone growth, thus Applicants allege that the inhibition of HMG-CoA reductase and osteoblastic differentiation is coincidental and does not demonstrate that administration of a non-statin HMG-CoA reductase inhibitor will induce osteoblastic differentiation. In addition, Applicants contend that Parish does not mention any effect of an oxysterol on bone formation, though Parish teaches that oxysterol is a HMG-CoA reductase inhibitor. As such, Applicants allege that "one of ordinary skill in the art would not be motivated to administer an oxysterol to induce

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osteoblastic differentiation, and would have no reasonable expectation of success in inducing osteoblastic differentiation by administering an oxysterol”. Such is not persuasive.

HMG-CoA reductase inhibitors including statins and other compounds having HMG-CoA reductase inhibitory activity promote bone growth and inhibit adipocyte differentiation. Both statins and side-chain oxysterols are reductase inhibitors. So if administration of a therapeutically effective amount of statins promotes bone growth and inhibits adipocyte differentiation, administration of a therapeutically effective amount of a side-chain oxysterol should be reasonably expected to promote bone growth and to inhibit adipocyte differentiation for the same reason statins promote bone growth – both compounds are HMG-CoA reductase inhibitors. Moreover, Applicants’ position that” inhibition of HMG-CoA reductase and osteoblastic differentiation are coincident effects of the administration of statins does not demonstrate that the inhibition of HMG-CoA reductase causes osteoblastic differentiation or that the administration of a non-statin HMG-CoA reductase inhibitor will induce osteoblastic differentiation” is not persuasive because Applicants’ opinion is unsupported by any specific or real evidence, while the options of the skill in the art are given respectful consideration, in the absence of any actual evidence of “unexpected results”, the opinions of the inventor do not overcome a case of *prima facie* obviousness. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See **MPEP § 716.01(c)** for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration. Examples of attorney statements

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which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. MPEP 716.01(c).

Provisional Rejection, Obviousness Type Double Patenting-

Claims 1-3, 6-8, 11, 12, 15-17, 19-21, 23-26 and 28 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, 11-15, 17-20, 22-25 and 27-30 of copending Application No. 10,569,994, in view of Paralkar et al., 20040176423 (Date of Publication September 9, 2004), for the reasons already of record as set forth in the office action of 06-11-2008.

Applicants have not properly address the specific grounds of rejection as discussed in the previous office action setting.

Claims 1-3, 6-8, 11, 12, 15-17, 19-21, 23-26 and 28 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 11/918,089 and over claims 1-9 and 15 of the copending Application No. 11/991,322, for the reasons already of record as set forth in the office action of 06-11-2008.

Applicants have not properly address the specific grounds of rejection as discussed in the previous office action setting.

Conclusion

Claims 1-3, 6-8, 11, 12, 15-17, 19-21, 23-26 and 28 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633